 FEB 2 1 2014

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-638-2954
Fax:	480-449-2546
Contact:	Sarah McCartney, Regulatory Affairs Specialist
Date:	January 23, 2014

2. Subject Device:

Device Trade Name:	Bard® Monopty® Disposable Core Biopsy Instrument Bard® Max-Core® Disposable Core Biopsy Instrument
Common or Usual Name:	Core Biopsy Instrument
Classification:	Class II
Classification Name:	Instrument, Biopsy (Product Code KNW)
Review Panel:	Gastroenterology / Urology
Regulation Number:	21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

3. Predicate Device:

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

4. Summary of Change:

This Special 510(k) provides an updated file to FDA including several changes that have occurred to the subject device since the predicate submission. These changes include updates to the labeling and the addition of a needle gauge size, addition of needle lengths, and addition of performance specifications.

5. Subject Device Description:

Bard® Monopty® Disposable Core Biopsy Instrument

The Bard® Monopty® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge, and Light Blue = 12 gauge.

Bard® Max-Core® Disposable Core Biopsy Instrument

The Bard® Max-Core® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge.

6. Indications for Use of Device:

The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Same patient-contacting materials
- Same fundamental scientific technology

- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes from the predicate submission, the subject devices and the predicate device are different in the following manner:

- Updated labeling
- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

8. Performance Testing Summary:

To verify that the device design met its functional and performance requirements, representative samples of the device underwent bench testing (dimensional, sample quality, durability, needle to device tensile strength, and echogenicity). Results of this testing demonstrate that the design outputs continue to meet the design inputs and user need requirements.

9. Conclusion:

Bard Peripheral Vascular, Inc. considers the subject devices to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Bard Peripheral Vascular, Inc.
Sarah McCartney
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, AZ 85281

Re: K133948
Trade/Device Name: Bard® Monopty® Disposable Core Biopsy Instrument
Bard® Max-Core® Disposable Core Biopsy Instrument
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: January 27, 2014
Received: January 28, 2014

Dear Sarah McCartney,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133948

Device Name: Bard® Monopty® Disposable Core Biopsy Instrument
Bard® Max-Core® Disposable Core Biopsy Instrument

Indications for Use: The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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